

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 6-11, 13, 16-18 and 25-34 are pending. Withdrawn claims 1-5 and 22-23 are canceled without prejudice or disclaimer to their later prosecution. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. The limitations of claims 12 and 14 are incorporated into independent claim 6. Support for a protein S polypeptide which is greater than 95% identical in amino acid sequence to human protein S may be found at page 16, lines 8-12, of the specification. Two specific diseases or pathological conditions that may be treated by the elected method are neurotrauma and stroke (see page 7, lines 22-23, of the specification) and are the basis of new independent claims 25 and 30.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 6-18 were rejected under Section 112, first paragraph, because the specification allegedly “does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.” Applicants traverse because describing the protein S polypeptide as greater than 95% identical to the amino acid sequence of a human protein S conforms with the enablement requirement. Applicants have provided a detailed disclosure of variations in the amino acid sequence of protein S and its structure-function relationships (see page 12-17 of the specification). The amino acid sequences of protein S were well known even though the level of sequence homology is modest:

At least partial sequences for protein S from human, monkey, mouse, rat, rabbit and cow are known. After alignment, they are about 59% identical at the amino acid level.

Page 11, lines 28-30, of the specification. Thus, administration of polypeptides which are greater than 95% sequence identity to a human protein S in Applicants' claimed invention is commensurate in scope with their extensive disclosure of protein S variants and its structure-function relationships in the present specification.

Withdrawal of the enablement rejection is requested because it would not require undue experimentation for a person of skill in the art to make and use the invention.

35 U.S.C. 112 – Written Description

The specification must convey with reasonable clarity to persons skilled in the art that applicant was in possession of the claimed invention as of the filing date sought. See *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). But the Patent Office has the initial burden of presenting evidence or a reason why persons of ordinary skill in the art would not have recognized such a description of the claimed invention in the original disclosure. See *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Claims 6-18 were rejected under Section 112, first paragraph, because they allegedly contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Applicants traverse because the specification teaches a representative number of species within the claimed genus. The polypeptide administered in the claimed method is greater than 95% identical to the amino acid sequence of a human protein S. Note that amino acid sequences of human protein S are known in the prior art. Therefore, their recitation in the specification is not required. See *Hybritech v. Monoclonal Antibodies*, 231 USPQ 81, 94 (Fed. Cir. 1986) ("A specification need not teach, and preferably omits, what is well known in the art"). Applicants have provided a detailed disclosure of variations in the amino acid sequence of protein S and its structure-function relationships (see page 12-17 of the specification). Since the level of sequence homology among the different species (i.e., human, monkey, mouse, rat, rabbit and cow) is modest, requiring greater

than 95% sequence identity to a human protein S is sufficient chemical structure to ensure an adequate written description of the protein S variants administered to the human subject.

Withdrawal of the written description rejection is requested because the specification conveys to a person skilled in the art that Applicants were in possession of the claimed invention as of the filing date.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 6-18 were rejected under Section 102(a) as anticipated by Cheng et al. (Soc. Neurosci. Abstract 390.13, available 19 Aug 2002). Applicants traverse because the invention was not described in a printed publication in this country before the invention thereof by the applicant for patent. Instead, the relevant disclosure of the cited document is by the same inventive entity as the inventors of this application. The disclosure of their own work within one year of the effective filing date of this application cannot be cited under Section 102(a). See *In re Katz*, 215 USPQ 14 (CCPA 1982).

Claims 6-13 and 15-17 were rejected under Section 102(b) as allegedly anticipated by Schwarz et al. (U.S. Patent 5,254,532). Applicants traverse because the limitation of claim 14 is incorporated in independent claim 6. The Examiner did not allege that the cited document teaches or renders obvious such treatment. Therefore, Schwarz does not disclose each and every limitation as set forth in the claim.

Claims 6 and 8-18 were rejected under Section 102(b) as allegedly anticipated by Hung (U.S. Appln. 2003/0060415). Applicants traverse because the limitation that the administered polypeptide is greater than 95% identical to the amino acid sequence of a human protein S is incorporated in independent claim 6. The Examiner did not

allege that the cited document teach or renders obvious such treatment. Therefore, Hung does not disclose each and every limitation as set forth in the claim.

Withdrawal of the Section 102 rejections is requested because the cited prior art documents fail to disclose all limitations of the claimed invention.

Double Patenting

Claims 6-11 and 13-18 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-6 of Patent No. 7,074,402. Applicants traverse because the limitation of claim 12 is incorporated in independent claim 6. The Examiner did not allege that the claims of the cited patent disclose such treatment. Therefore, the '402 patent does not disclose each and every limitation as set forth in the claim. Note that this application and the cited patent are not commonly owned.

Withdrawal of the double patenting rejection is requested.


Conclusion

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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